PATENT COOPERATION TREATY From the INTERNATIONAL SEARCHING AUTHORITY To: see form PCT/ISA/220 Date of mailing Applicant's or agent's file reference

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

(day/month/year) see form PCT/ISA/210 (second sheet)

see form PCT/ISA/220

FOR FURTHER ACTION See paragraph 2 below

International application No. PCT/US2007/011321

International filing date (day/month/year)

10.05.2007 11.05.2006

Priority date (day/month/year)

International Patent Classification (IPC) or both national classification and IPC INV. A61M1/00 A61M27/00

Applicant

IASIS MEDICAL, LLC

This opinion contains indications relating to the following items: 1.

Box No. I Basis of the opinion

☐ Box No. II Priority

☑ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

☐ Box No. IV Lack of unity of invention

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial

applicability; citations and explanations supporting such statement

☐ Box No. VI Certain documents cited

☐ Box No. VII Certain defects in the international application

Box No. VIII Certain observations on the international application

FURTHER ACTION 2.

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:

Date of completion of this opinion

Authorized Officer

European Patent Office - P.B. 5818 Patentlaage form NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016

PCT/ISA/210

Lakkis, Angeliki

Telephone No. +31 70 340-4136



WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/US2007/011321

	Box	ox No. I Basis of the opinion		
1.	1. With regard to the language, this opinion has been established on the basis of:			
	\boxtimes	the international application in the language in which it was filed		
ļ		a translation of the international application into , which is the language of a translation furnish purposes of international search (Rules 12.3(a) and 23.1 (b)).	ed for the	
2.		This opinion has been established taking into account the rectification of an obvious mistake by or notified to this Authority under Rule 91 (Rule 43bis.1(a))	authorized	
 With regard to any nucleotide and/or amino acid sequence disclosed in the international application necessary to the claimed invention, this opinion has been established on the basis of: 			ion and	
;	a. type of material:			
		□ a sequence listing		
		□ table(s) related to the sequence listing		
ı	b. fc	format of material:		
		□ on paper		
	Е	□ in electronic form		
(e. tir	ime of filing/furnishing:		
		\square contained in the international application as filed.		
		\square filed together with the international application in electronic form.		
		\Box furnished subsequently to this Authority for the purposes of search.		
4. [In addition, in the case that more than one version or copy of a sequence listing and/or table rel has been filed or furnished, the required statements that the information in the subsequent or a copies is identical to that in the application as filed or does not go beyond the application as file appropriate, were furnished.	dditional	
5. 4	Addi	ditional comments:		

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/US2007/011321

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability				
The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of				
	the entire international application			
	claims Nos. 41			
because:				
	the said international application, or the said claims Nos. $\underline{41}$ relate to the following subject matter which does not require an international search (specify):			
	see separate sheet			
	the description, claims or drawings (indicate particular elements below) or said claims Nos. are so unclear that no meaningful opinion could be formed (specify):			
	the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (specify):			
\boxtimes	international search report has been established for the whole application or for said claims Nos. 41			
	a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:			
	furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.			
	furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.			
	pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13 <i>ter</i> .1(a) or (b).			
	a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.			
	tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not apply with the technical requirements provided for in Annex C- <i>bis</i> of the Administrative Instructions.			
	See Supplemental Box for further details			

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/US2007/011321

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes: Claims

8, 9, 16-24, 26, 29, 30, 39, 40

No: Claims

1-7, 10-15, 25, 27, 28, 31-38

Inventive step (IS)

Yes: Claims

No: Claims

1-40

Industrial applicability (IA)

Yes: Claims

<u>1-40</u>

No: Claims

2. Citations and explanations

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Form PCT/ISA/237 (April 2007)

Re Item III.

Claim 41: Rule 6.2(a) PCT

Re Item V.

1 Reference is made to the following documents:

D1: US 2001/029956 A1 (ARGENTA LOUIS C [US] ET AL) 18 October 2001 (2001-10-18)

D2: FR 1 163 907 A (WALTER PAUL) 2 October 1958 (1958-10-02)

D3: US 2003/040687 A1 (BOYNTON THOMAS A [US] ET AL BOYNTON THOMAS A [US] ET AL) 27 February 2003 (2003-02-27)

2 INDEPENDENT CLAIM 1

2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

Document D1 (paragraphs 31, 32, 40, 42, figures 1, 2, 8) (discloses (the references in parentheses applying to this document):

A wound therapy device, comprising a housing (58) to cover at least a portion of a wound, a liquid retention chamber positioned inside of the housing (interior space of 58) and a vacuum connection (distal end of 30a), the vacuum connection in gaseous communication with the liquid-retention chamber, the vacuum connection being separated from the liquid-retention chamber by a liquid barrier (38a).

- 2.2 Document D2 also discloses all the technical features of claim 1 (see whole page 1, especially the liquid barrier can be identified either as the cotton (3) or as the cock (5)) so that the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT over D2, either.
- 3 INDEPENDENT CLAIMS 31, 36

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (SEPARATE SHEET)

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The subject-matter of claims 31 and 36 is not new over either D1 or D2 or D3 (see passages as above and cited in the search report). The reasons are as above under 2.1 and 2.2. and, for the means for preventing collapse in claim 38, see the rigidity of the housings. Therefore the present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 31 and 36 is not new in the sense of Article 33(2) PCT.

DEPENDENT CLAIMS 2-30, 32-35, 37-40
Dependent claims 2-30, 32-35, 37-40 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT), see the cited documents and passages and the common knowledge in the field of wound drainage.

Re Item VIII.

- 5.1 Claim 5 is unclear (Article 6 PCT) since it relates to a "flexible barrier" whereby it is not clear whether the "liquid barrier" defined in claim 1 is meant or a different, additional one.
- 5.2 Independent claims 1, 31, 36 all relate to a wound therapy device, making the scope of protection unclear (Article 6 PCT).